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**EXPRESS MAIL CERTIFICATE**

DOCKET NO.: 176/61702

APPLICANT(S): FAY et al.

TITLE: RECOMBINANT FACTOR VIII HAVING INCREASED SPECIFIC ACTIVITY

Certificate is attached to the Information Disclosure Statement, Form SB-08, PCT Search Report and 4 references of the above-named application.


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PATENT

Docket No.: 176/61702

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicants:	FAY et al.	)
		)
U. S. Serial No:	To be assigned	)
		)
Filed:	Herewith	)
		)
PCT International		)
Application No:	PCT/US2004/040234	)
		)
Filed:	2 December 2004	)
		)
For:	RECOMBINANT FACTOR VIII	)
	HAVING INCREASED SPECIFIC	)
	ACTIVITY	)

INFORMATION DISCLOSURE STATEMENT  
UNDER 37 CFR §§ 1.97-1.98

**Mail Stop: PCT**  
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Dear Sir:

In compliance with 37 C.F.R. 1.56, 1.97, and 1.98, published art are cited for consideration and listed on the enclosed PTO/SB/08 form.

References 1, 2 and 19-25 were cited in the International Search Report (copy enclosed) of the corresponding PCT application. These references are relevant for the reasons given in the report. Because copies of these references should have been transferred by the International Searching Authority, duplicate copies are not enclosed herewith.

References 3-18 are U.S. Patent documents and, therefore, copies of these references are not enclosed herewith.


Copies of references 26-29 are enclosed herewith.

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It is respectfully requested that an Examiner-initialed copy of this form be returned to the undersigned.

Respectfully submitted,

Date: June 1, 2006

  
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PTO/SB/08A (10-01)

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Substitute for form 1449A/PTO  <b>INFORMATION DISCLOSURE STATEMENT BY APPLICANT</b>  <i>(use as many sheets as necessary)</i>				<i>Complete if Known</i>	
				Application Number	To Be Assigned
				Filing Date	Herewith
				First Named Inventor	Philip FAY
				Art Unit	To Be Assigned
				Examiner Name	To Be Assigned
				Attorney Docket Number	176/61702
Sheet	1	of	2		

U.S. PATENT DOCUMENTS					
Examiner Initials*	Cite No. <sup>1</sup>	U.S. Patent Document	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
		Number - Kind Code <sup>2</sup> (if known)			
	1	US 5,859,204 A	01-12-1999	Lollar	
	2	US 6,759,216 B1	07-06-2004	Lollar	
	3	US 6,780,614	08-24-2004	Négrier et al.	
	4	US 6,800,461	10-05-2004	Négrier et al.	
	5	US 6,271,025	08-07-2001	Négrier et al.	
	6	US 5,576,291	11-19-1996	Curtis et al.	
	7	US 5,880,327	03-09-1999	Lubon et al.	
	8	US 5,998,589	12-07-1999	Buettner et al.	
	9	US 6,376,463	04-23-2002	Lollar	
	10	US 6,593,291	07-15-2003	Green et al.	
	11	US 6,599,724	07-29-2003	Mikaelsson et al.	
	12	US 6,458,563	10-01-2002	Lollar	
	13	US 6,770,744	08-03-2004	Lollar	
	14	US 2004/0197815 A1	10-07-2004	Hauser et al.	
	15	US 2003/0125232 A1	07-03-2003	Griffin et al.	
	16	US 2003/0166536 A1	09-04-2003	Lollar et al.	
	17	US 2004/0092442 A1	05-13-2004	Kaufman et al.	
	18	US 2004/0147436 A1	07-29-2004	Kim et al.	

[illegible]

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<sup>1</sup> Applicant's unique citation designation number (optional). <sup>2</sup> See Kinds Codes of USPTO Patent Documents at [222.uspto.gov](http://222.uspto.gov) or MPEP 901.04. <sup>3</sup> Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). <sup>4</sup> For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. <sup>5</sup> Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST.16 if possible. <sup>6</sup> Applicant is to place a check mark here if English language Translation is attached.

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Substitute for form 1449A/PTO				<b>Complete if Known</b>	
<b>INFORMATION DISCLOSURE STATEMENT BY APPLICANT</b> <i>(use as many sheets as necessary)</i>				Application Number	To Be Assigned
				Filing Date	Herewith
				First Named Inventor	Philip FAY
				Art Unit	To Be Assigned
				Examiner Name	To Be Assigned
Sheet	2	of	2	Attorney Docket Number	176/61702

OTHER PRIOR ART – NON PATENT LITERATURE DOCUMENTS				
Examiner Initials*	Cite No. <sup>1</sup>	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.		T <sup>2</sup>
	19	WAKABAYASHI et al., "Residues 110-126 in the Factor VIII Heavy Chain Contain a CA2+ Binding Site Required for Cofactor Activity," <i>Blood</i> 102(11):542a (2003).		
	20	AMANO et al., "Mutation at either ARg336 or Arg562 in Factor VIII is Insufficient for Complete Resistance to Activated Protein C (APC)-Mediated Inactivation: Implications for the APC Resistance Test," <i>Thromb Haemost</i> 79:557-563 (1998).		
	21	SWAROOP et al., "Mutagenesis of Potential Immunoglobulin-Binding Protein-Binding Site Enhances Secretion of Coagulation Factor VIII," <i>J Biol Chem</i> 272(39):24121-24124 (1997).		
	22	WAKABAYASHI et al., "Factor VIII: E113A Represents a High Specific Activity Factor VIII Arising From a Single Point Mutation within the Ca2+ Binding Site," <i>Blood</i> 104(11):479a (2004).		
	23	WAKABAYASHI et al., "Residues 110-126 in the A1 Domain of Factor VIII Contain a Ca2+ Binding Site Required for Cofactor Activity," <i>J Biol Chem</i> 279(13):12677-12684 (2004).		
	24	SARAFANOV et al., "Cell Surface Heparan Sulfate Proteoglycans Participate in Factor VIII Catabolism Mediated by Low Density Lipoprotein Receptor-Related Protein," <i>J Biol Chem</i> 276(15):11970-11979 (2001).		
	25	LENTING et al., "The Sequence of Glu1811-Lys1818 of Human Blood Coagulation Factor VIII Comprises a Binding Site for Activated Factor IX," <i>J Biol Chem</i> 271(4):1935-1940 (1996).		
	26	GALE et al., "An Engineered Interdomain Disulfide Bond Stabilizes Human Blood Coagulation Factor VIIIa," <i>J Thrombosis and Haemostasis</i> 1(9):1966-1971 (2003) (abstract only).		
	27	PIPE et al., "Characterization of a Genetically Engineered Inactivation-Resistant Coagulation Factor VIIIa," <i>Proc Natl Acad Sci USA</i> 94:11851-11856 (1997).		
	28	LENTING et al., "The Life Cycle of Coagulation Factor VIII in View of Its Structure and Function," <i>Blood</i> 92(11):3983-3996 (1998)		
	29	HERNÁNDEZ (editor), "Factor VIII/von Willebrand Factor Complex in Hemophilia A Treatment Recent Findings, Emerging Major Role," <i>Journal of Hematology</i> 88(9):1-27 (2003).		

Examiner Signature		Date Considered	
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